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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

MAR 2 0 2002

Applicant

: Scott Daniel Hofmann

TECH CENTER 1600/2900

Appl. No.

: 09/974,648

Filed

: October 9, 2001

Title

: Diagnostic Polymerase Chain Reaction

Utilizing Simultaneous Capture and Detection

of Amplicons

Examiner

: To be assigned

Group Art Unit: 1645

### RESPONSE TO NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATION CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Hon. Commissioner of Patents and Trademarks Washington, DC 20231

#### sir:

In response to the Notice to Comply with Requirements for Patent Application Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures dated November 5, 2001, the following remarks are made:

The Examiner stated that "This application clearly fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825."

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However, Section 1.821(a) states, "Nucleotide and/or amino acid sequences as used in §§ 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides."

Section 1.821 does not apply to the instant application because no unbranched sequence of four or more amino acids or ten or more nucleotides is named.

The invention generally relates to a process for quantitatively and qualitatively counting any genetic sequence. The actual content of a particular sequences being detected is not relevant to the invention. In addition, the reagents of the invention have no particular sequence but are only defined by the analyte. Accordingly, to require specific sequences would unnecessarily narrow the scope of the invention.

For these reasons, 37 C.F.R. 1.821 does not apply to the instant application. Therefore, no sequence is required.

A copy of the Notice is enclosed.

Petition for extension is herewith made. The extension fee for response within a period of two months pursuant to Section

1.136(a) in the amount of \$200 for a small entity may be withdrawn from deposit account 12-1099.

Please charge any other fees that might be due with respect to Sections 1.16 and 1.17 to the Deposit Account of Lerner and Greenberg, P.A., No. 12-1099.

Respectfully submitted,

LOREN DONALD PEARSON REG. NO. 42,987

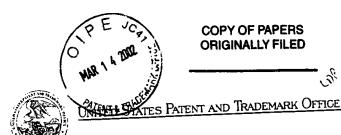
For Applicant(s)

LDP:cgm

March 5, 2002

Lerner and Greenberg, P.A. Post Office Box 2480 Hollywood, FL 33022-2480

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APPLICATION NUMBER

FILING RECEIPT DATE

FIRST NAMED APPLICANT

ATTORNEY DOCKET NUMBER

09/974,648

10/09/2001

Scott Daniel Hofmann

WHS-7917

**CONFIRMATION NO. 9983** 

FORMALITIES LETTER 

LERNER AND GREENBERG, P.A. POST OFFICE BOX 2480 HOLLYWOOD, FL 33022-2480

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Date Mailed: 11/05/2001

### NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE **DISCLOSURES**

Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

 This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase Patentin Software, call (703) 306-2600
- For Patentin Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

A copy of this notice <u>MUST</u> be returned with the reply.	
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PART 2 - COPY TO BE RETURNED WITH RESPONSE

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WASHINGTON, D.C. 2023

### Attachment to Notice of Incomplete Reply

This is in response to Applicant's remarks regarding sequence rule compliance in the instant application. An application that contains generic techniques to determine DNA sequence information such as DNA molecule length or nucleotide composition, without disclosing specific sequences, would not have to comply with the sequence rules. The instant application, however, also discloses specific sequences. The facts that no sequences are claimed and any specific sequence mentioned would be used solely for illustrative purposes and not represent a novel sequence disclosure are immaterial. Any sequence that is disclosed must be submitted in accordance with 37 CFR 1.821-825. That is the meaning of the "exclusively" language.

Sequences were found at page(s) \_\_\_\_\_, and/or Figure \_\_\_\_\_.